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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/678,652

Applicant(s)

OSHIDA ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 18-29 and 36-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 18-29 and 36-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1-11, 18-29 and 36-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,830,645 (Pinkel et al.) in view of US Patent 5,981,956 (Stern), US Patent 4,538,613 (Rosenberg), and US Patent 5,874,219 (Rava et al.).

5. Pinkel et al., column 12, second full paragraph, discloses a method of inspecting a coupled state of hybridized target DNA on a DNA chip wherein the DNA is arranged on the chip in a predetermined array. The method comprises causing fluorescently labeled DNA probe cells to fluoresce and said fluorescent signals are detected by means of a CCD camera (applicant's "sensor") and the storage and analysis of signals produced by the label bound to the "DNA probe cells" that correspond to the position(s) of the array.

6. The aspect of having the nucleic acid array (applicant's DNA cells) in an array speaks to the cells being in a one- or two-dimension.

7. Pinkel et al., column 12, teach using a bean splitter. as well as using a computer to analyze the signals so as to obtain information from the DNA chip.

8. Pinkel et al., do not disclose the time of illumination or the size of the spots the areas of illumination and how that relates to the areas where probe and target DNA are immobilized.

9. Stern, column 10, teaches of detecting fluorescent signals resulting from DNA hybridization reactions where DNA is immobilized to areas of an array. Column 10, lines 21-28, teaches "simultaneous interrogation of a single array with multiple target sequence" and the simultaneous detection of multiple fluorescent signals as a result of using bean splitters. Column 10, second paragraph, teaches "directing" the fluorescent signal to detectors (applicant's sensor") such that the signal is detected, measured, and recorded.

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10. Stern, column 9, first full paragraph, teaches explicitly of spot size (applicant's "multi-spot excitation lights").

11. Stern, column 11, teaches of using fluorescently labeled DNA or RNA that is hybridized to oligonucleotides. Also disclosed therein is the use of a beam splitter

12. Rosenberg, column 19, teaches using laser light that has been split or chopped such that multiple beams can be projected along desired paths toward (or away from the target site.

Rosenberg also disclose that the "micro-objective and piezoelectric elements may function either jointly, sequentially, or simultaneously to direct one or more beams (applicant's "multi-spot excitation lights") onto the fiber array (applicant's "optical paths").

13. Rava et al., column 6, disclose a method whereby the coupled state of hybridized target DNA on a DNA chip is conducted in a simultaneous manner.

14. As seen in one embodiment found in column 6, the probe can be immobilized to the chip while the target DNA is labeled with a fluorescent label.

15. Rava et al., column 6, also teach inspecting the DNA cells in a 1-dimensional manner, as well as employing a multi-axis translation stage wherein the light source may be a laser. Such a limitation speaks to conducting the inspection in a 2-dimensional manner.

16. Column 6, last paragraph, teaches explicitly of optionally using a 2-dimensional array of sensors (light detectors). At lines 50-51, Rava et al., teach that image of the cells can be stored in a computer.

17. Also disclosed is the utilization of rotating polyhedral mirrors to effect simultaneous scanning of a plurality of excitation lights (applicant's fluorescent label).

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18. In view of the totality of the teachings of the prior art of record, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Rosenberg with that of Stern, Pinkel et al., and Rava as such would have allowed the ordinary artisan the capacity to simultaneously inspect multiple positions of an array where fluorescently labeled target DNA have hybridized (coupled) to a probe, and to thereby obtain information about the strength of such coupling, to store (catalog) such information in a computer system for later analysis and retrieval. In view of the detailed teaching of splitting excitation light, as well as the capture of fluorescent signals from a multitude of positions in a simultaneous manner, the ordinary artisan would have been amply motivated to combine that technology that would have allowed for increased simultaneous signal processing and to have had a most reasonable expectation of success in being able to accurately interrogate such positions and resulting signals.

19. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-11, 18-29 and 36-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,830,645 (Pinkel et al.) in view of US Patent 5,981,956 (Stern), US Patent 4,538,613 (Rosenberg), and US Patent 5,874,219 (Rava et al.).

Response to argument

20. At page 19, bridging to page 20, of the response received 21 March 2005, hereinafter the response, applicant's representative asserts that the claimed invention is directed to "improved arrangements for inspecting a coupled state of hybridized target DNA on a DNA chip. More particularly, in considering disadvantaged arrangements, Applicant found un acceptable inspection speeds, noise and/or complexities." Applicant's representative further argues that a

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“disadvantage arrangement [existed when] using multiple pixels (i.e., a sub-array) of a photomultiplier tube and/or CCD detector to detect each probe cell was found (by Applicant) to suffer unacceptable inspection speeds, noise ratios and complexities” (emphasis in the original).

21. The above argument has been fully considered and has not been found persuasive. As an initial matter, it is noted that none of the claims are drafted in a Jepson format, where they are directed to an asserted improvement. It is further noted that none of the claims exclude the use of a sub-array and/or CCD detector. In short, none of the claims contain any limitation as to inspection speeds, or noise ratios and/or complexities. Therefore, and in the absence of convincing evidence to the contrary, the rejection is maintained.

22. At page 20, last paragraph, applicant’s representative asserts that applicant invented the concept of scanning and detecting multiple probe cells at the same time.

23. The above argument has not been found persuasive for as seen above in the cited prior art, Stern teaches at column 10 the “simultaneous interrogation of a single array with multiple target sequence” and the simultaneous detection of multiple fluorescent signals as a result of using beam splitters, including “directing” the fluorescent signal to detectors (applicant’s sensor”) such that the signal is detected, measured, and recorded.

24. At page 21 applicant’s representative asserts that there can be a 10-fold increase in speed of the assay. However, as noted above, the claims do not recite any limitation as to speed.

Accordingly, the claimed assay can be conducted as fast, faster or infinitely slower than that of the prior art. In short, applicant is arguing limitations not recited in the claims.

25. Agreement is reached with applicant’s representative at page 24 in that no one piece of cited art teaches all elements of the claimed invention. It is noted, however, that the claims have

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not been rejected under 35 USC 102, which relates to matters of anticipation, but rather under 35 USC 103(a), which relates to matters of obviousness.

26. Agreement is reached in that the Rava et al., do teach using sensors that correspond to each of the DNA probe cell irradiated. While Rava et al., does not use multi-spots, such would have been obvious to one of skill in the art as Rosenberg, column 19, teaches using laser light that has been split or chopped such that multiple beams can be projected along desired paths toward (or away from the target site. Rosenberg also disclose that the “micro-objective and piezoelectric elements may function either jointly, sequentially, or simultaneously to direct one or more beams (applicant’s “multi-spot excitation lights”) onto the fiber array (applicant’s “optical paths”).

27. In response to applicant's argument that Rosenberg is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Pinkel and Stern each teach of generating light beams that can be split and directed to target areas of interest, the signal generated being detected through sensors, which as disclosed by Rava, can be arranged in a 2-dimensional manner such that specific sensors correspond to specific DNA probe cells wherein the light source may be a laser. Rosenberg teaches that the same light used by Rava, a laser, may be split through use of a beam splitter (disclosed by Pinkel and Stern), and then directed to the target site. In view of such a showing, one of ordinary skill in the art would have been motivated to have used a split beam of light, be it laser (Rosenberg) or otherwise, (Pinkel or Stern) such that

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discrete spots (Stern) are directed to individual DNA cells, thereby allowing for signal generation and detection on a DNA cell-specific basis.

28. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

30. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
06 April 2005